

Claims

1. Pharmaceutical composition intended for the treatment or prevention of a papillomavirus infection or tumor, which comprises, as therapeutic agents:
 - 5 (1) at least one polypeptide from the early region of a papillomavirus and at least one polypeptide from the late region of a papillomavirus,
 - (2) at least one polypeptide from the early region of a papillomavirus, at least one polypeptide from the late region of a papillomavirus and at least one polypeptide having immunostimulatory activity, or
 - 10 (3) at least one polypeptide from an early or late region of a papillomavirus and at least one polypeptide having immunostimulatory activity.
- 15 2. Pharmaceutical composition according to Claim 1, characterized in that the polypeptide from the early region of a papillomavirus is derived from the E6 protein, from the E7 protein or from the E6 and E7 proteins of a papillomavirus.
- 20 3. Pharmaceutical composition according to Claim 2, characterized in that the polypeptide from the early region of a papillomavirus is a nononcogenic variant of the E6 and/or E7 protein of a papillomavirus.
4. Pharmaceutical composition according to one of
- 25 Claims 1 to 3, characterized in that the polypeptide from the late region of a papillomavirus is derived from the L1 protein, from the L2 protein or from the L1 and L2 proteins.
5. Pharmaceutical composition according to one of
- 30 Claims 1 to 4, characterized in that the polypeptide having an immunostimulatory activity is selected from the group consisting of interleukin-2, interleukin-7, interleukin-12 and the co-adhesion molecules B7.1 and B7.2.
- 35 6. Pharmaceutical composition according to Claim 5, characterized in that the polypeptide having immunostimulatory activity is derived from interleukin-2.

7. Pharmaceutical composition according to Claim 5 or 6, characterized in that the polypeptide having immunostimulatory activity is derived from the molecule B7.1.

8. Pharmaceutical composition according to one of Claims 1 to 7, characterized in that it comprises:

(1) a polypeptide from the E6 region, a polypeptide from the E7 region, a polypeptide from the L1 region and a polypeptide from the L2 region of a papilloma-virus,

(2) a polypeptide from the E6 region, a polypeptide from the E7 region of a papillomavirus and a polypeptide derived from interleukin-2,

(3) a polypeptide from the E6 region, a polypeptide from the E7 region of a papillomavirus and a polypeptide derived from the molecule B7.1,

(4) a polypeptide from the E6 region, a polypeptide from the E7 region of a papillomavirus, a polypeptide derived from the molecule B7.1 and a polypeptide derived from interleukin-2,

(5) a polypeptide from the E6 region, a polypeptide from the E7 region, a polypeptide from the L1 region, a polypeptide from the L2 region of a papillomavirus and a polypeptide derived from interleukin-2,

(6) a polypeptide from the E6 region, a polypeptide from the E7 region, a polypeptide from the L1 region, a polypeptide from the L2 region of a papillomavirus and a polypeptide derived from the molecule B7.1, or

(7) a polypeptide from the E6 region, a polypeptide from the E7 region, a polypeptide from the L1 region, a polypeptide from the L2 region of a papillomavirus, a polypeptide derived from the molecule B7.1 and a polypeptide derived from interleukin-2.

9. Pharmaceutical composition according to one of Claims 1 to 8, characterized in that the papillomavirus is selected from the HPV-16, HPV-18, HPV-31, HPV-33 and/or HPV-45 types.

10. Pharmaceutical composition intended for the treatment or prevention of a papillomavirus infection or

tumor, which comprises, as therapeutic agent(s), one or more recombinant vectors into which there are inserted DNA fragments coding for:

- (1) at least one polypeptide from the early region of a papillomavirus and at least one polypeptide from the late region of a papillomavirus,
- (2) at least one polypeptide from the early region of a papillomavirus, at least one polypeptide from the late region of a papillomavirus and at least one polypeptide having an immunostimulatory activity, or
- (3) at least one polypeptide from an early or late region of a papillomavirus and at least one polypeptide having an immunostimulatory activity;

said DNA fragments being placed under the control of the elements necessary for their expression in a host cell or organism.

11. Pharmaceutical composition according to Claim 10, characterized in that said polypeptides have the characteristics defined in Claims 2 to 9.

12. ^{wherein} ~~or 11, characterized in that~~ the recombinant vector is a viral vector which can be derived from the genome of a virus selected from poxviruses, adenoviruses, retroviruses, herpesviruses and adeno-associated viruses.

13. ^{wherein} ~~characterized in that~~ the recombinant vector is derived from a poxvirus selected from the group consisting of vaccinia virus, canarypox virus and fowlpox virus.

14. ^{wherein} ~~characterized in that~~ the recombinant vector is derived from a vaccinia virus selected from the Copenhagen, Wyeth and modified Ankara (MVA) strains.

15. ^{wherein} ~~or 14, characterized in that~~ the elements essential for the expression of the DNA fragments coding for said polypeptides comprise a promoter of a gene of a vaccinia virus selected from the promoters of the thymidine kinase (TK), 7.5K, H5R and K1L genes.

16. Pharmaceutical composition according to Claim 14,

wherein

or 15, characterized in that the recombinant vector is derived from a vaccinia virus of the Copenhagen strain and in that the DNA fragments coding for said polypeptides are inserted into the TK locus and/or the K1L locus of said vaccinia virus.

17. Pharmaceutical composition according to Claim 14, wherein or 15, characterized in that the recombinant vector is derived from a vaccinia virus of the MVA strain and in that the DNA fragments coding for said polypeptides are inserted at the level of any of the excision zones selected from the I, II, III, IV, V and VI excisions of said vaccinia virus.

18. Pharmaceutical composition according to one of Claims 10 to 17, intended for the treatment or prevention of a papillomavirus infection or tumor, characterized in that it comprises one or more recombinant vectors derived from the Copenhagen or MVA strain of a vaccinia virus into which there are inserted:

(1) a DNA fragment coding for the E6 protein of a papillomavirus, a DNA fragment coding for the E7 protein of a papillomavirus and a DNA fragment coding for the molecule B7.1,

(2) a DNA fragment coding for the E6 protein of a papillomavirus, a DNA fragment coding for the E7 protein of a papillomavirus and a DNA fragment coding for interleukin-2,

(3) a DNA fragment coding for the E6 protein of a papillomavirus, a DNA fragment coding for the E7 protein of a papillomavirus, a DNA fragment coding for the molecule B7.1 and a DNA fragment coding for interleukin-2,

(4) a DNA fragment coding for the E6 protein of a papillomavirus, a DNA fragment coding for the E7 protein of a papillomavirus, a DNA fragment coding for the L1 protein of a papillomavirus and a DNA fragment coding for the L2 protein of a papillomavirus,

(5) a DNA fragment coding for the E6 protein of a papillomavirus, a DNA fragment coding for the E7

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protein of a papillomavirus, a DNA fragment coding for the L1 protein of a papillomavirus, a DNA fragment coding for the L2 protein of a papillomavirus and a DNA fragment coding for the molecule B7.1,

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(6) a DNA fragment coding for the E6 protein of a papillomavirus, a DNA fragment coding for the E7 protein of a papillomavirus, a DNA fragment coding for the L1 protein of a papillomavirus, a DNA fragment coding for the L2 protein of a papillomavirus and a DNA fragment coding for interleukin-2, or

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(7) a DNA fragment coding for the E6 protein of a papillomavirus, a DNA fragment coding for the E7 protein of a papillomavirus, a DNA fragment coding for the L1 protein of a papillomavirus, a DNA fragment coding for the L2 protein of a papillomavirus, a DNA fragment coding for the molecule B7.1 and a DNA fragment coding for interleukin-2.

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19. Pharmaceutical composition according to ~~one of~~ Claims 10 to 17, intended for the prevention of a papillomavirus infection or tumor, characterized in that it comprises one or more recombinant vectors derived from the Copenhagen or MVA strain of a vaccinia virus, into which there are inserted:

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(1) a DNA fragment coding for the L1 protein of a papillomavirus, a DNA fragment coding for the L2 protein of a papillomavirus and a DNA fragment coding for the molecule B7.1,

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(2) a DNA fragment coding for the L1 protein of a papillomavirus, a DNA fragment coding for the L2 protein of a papillomavirus and a DNA fragment coding for interleukin-2, or

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(3) a DNA fragment coding for the L1 protein of a papillomavirus, a DNA fragment coding for the L2 protein of a papillomavirus, a DNA fragment coding for interleukin-2 and a DNA fragment coding for the molecule B7.1.

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20. Pharmaceutical composition according to ~~one of~~

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add B27

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